

changes to, or clarification of, the substance of the memorandum, the request must be sent to FDA within 30 calendar days from the date a copy of the memorandum is sent to the applicant. If the potential applicant requests changes or clarification, FDA will send the potential applicant a response to their request no later than 45 calendar days after the date of receipt of the request.

(iv) *Administrative record.* A copy of FDA's original memorandum of conference and, as appropriate, a copy of an amended memorandum to correct or clarify the content of the original memorandum will be made part of the administrative file.

(2) *Field studies.* If FDA requires more than one field study to establish by substantial evidence that the new animal drug is effective for its intended uses under the conditions of use prescribed, recommended, or suggested in the proposed labeling, FDA will provide written scientific justification for requiring more than one field study. Such justification must be provided no later than 25 calendar days after the date of the conference at which the requirement for more than one field study is established. If FDA does not believe more than one field study is required but the potential applicant voluntarily proposes to conduct more than one field study, FDA will not provide such written justification. If FDA requires one field study to be conducted at multiple locations, FDA will provide justification for requiring multiple locations verbally during the pre-submission conference and in writing as part of the memorandum of conference.

(g) *Modification of presubmission conference agreements.* An agreement made under a presubmission conference requested under section 512(b)(3) of the act and documented in a memorandum of conference is binding on the potential applicant and FDA and may only be modified if:

(1) FDA and the potential applicant mutually agree to modify, in part or in whole, the agreement and such modification is documented and provided to the potential applicant as described in paragraph (f)(1) of this section; or

(2) FDA by written order determines that a substantiated scientific requirement essential to the determination of safety or effectiveness of the new animal drug appeared after the conference.

(h) *When the terms of a presubmission conference agreement are not valid—*(1) A presubmission conference agreement will no longer be valid if:

(i) The potential applicant makes to FDA, before, during, or after the pre-submission conference, any untrue statement of material fact; or

(ii) The potential applicant fails to follow any material term of the agreement; and

(2) A presubmission conference may no longer be valid if the potential applicant submits false or misleading data relating to a new animal drug to FDA.

(i) *Dispute resolution.* FDA is committed to resolving differences between a potential applicant and FDA reviewing divisions with respect to requirements for the investigation of new animal drugs and for NADAs, supplemental NADAs, and ANADAs as quickly and amicably as possible through a cooperative exchange of information and views. When administrative or procedural disputes arise, a potential applicant should first attempt to resolve the matter within the appropriate review division beginning with the individual(s) most directly assigned to the review of the application or investigational exemption. If the dispute cannot be resolved after such attempts, the dispute shall be evaluated and administered in accordance with applicable regulations (21 CFR 10.75). Dispute resolution procedures may be further explained by guidance available from the Center for Veterinary Medicine.

[69 FR 51170, Aug. 18, 2004]

#### §514.6 Amended applications.

The applicant may submit an amendment to an application that is pending, including changes that may alter the conditions of use, the labeling, safety, effectiveness, identity, strength, quality, or purity of the drug or the adequacy of the manufacturing methods, facilities, and controls to preserve

them, in which case the unamended application may be considered as withdrawn and the amended application may be considered resubmitted on the date on which the amendment is received by the Food and Drug Administration. The applicant will be notified of such date.

**§ 514.7 Withdrawal of applications without prejudice.**

The sponsor may withdraw his pending application from consideration as a new animal drug application upon written notification to the Food and Drug Administration. Such withdrawal may be made without prejudice to a future filing. Upon resubmission, the time limitation will begin to run from the date the resubmission is received by the Food and Drug Administration. The original application will be retained by the Food and Drug Administration although it is considered withdrawn. The applicant shall be furnished a copy at cost on request.

**§ 514.8 Supplemental new animal drug applications.**

(a)(1) After a new animal drug application is approved, a supplemental new animal drug application may propose changes. A supplemental application may omit statements made in the approved application concerning which no change is proposed. Each supplemental application shall include up-to-date reports of any of the kinds of information required by § 514.80 that has not previously been submitted. A supplemental application shall be accompanied by either a claim for categorical exclusion under § 25.30 or § 25.33 of this chapter or an environmental assessment under § 25.40 of this chapter.

(2) A supplemental new animal drug application shall be submitted for any change beyond the variations provided for in the application, including changes in the scale of production such as from pilot-plant to production batch, that may alter the conditions of use, the labeling, safety, effectiveness, identity, strength, quality, or purity of the new animal drug, or the adequacy of the manufacturing methods, facilities, or controls to preserve them.

(3) If it is a prescription drug, any mailing or promotional piece used

after the drug is placed on the market is labeling requiring a supplemental application, unless:

(i) The parts of the labeling furnishing directions, warnings, and information for use of the drug are the same in language and emphasis as labeling approved or permitted; and

(ii) Any other parts of the labeling are consistent with and not contrary to such approved or permitted labeling.

(4) The supplemental application shall be submitted as follows. A communication proposing a change in a new animal drug application should provide for any one of the following kinds of changes:

(i) Revision in labeling, such as updating information pertaining to effects, dosages, and side effects and contraindications, which includes information headed "side effects," "warnings," "precautions," and "contraindications."

(ii) Addition of claim.

(iii) Revision in manufacturing or control procedures; for example, changes in components, composition, method of manufacture, analytical control procedures, package or tablet size, etc.

(iv) Change in manufacturing facilities.

(v) Provision for outside firm to participate in the preparation, distribution, or packaging of a new animal drug (new distributor, packer, supplier, manufacturer, etc.); one firm per submission.

Any number of changes may be submitted at any one time; but if they fall into different categories as listed in paragraphs (a)(4) (i) through (v) of this section, the proposed changes should be covered by separate communications. Where, however, a change necessitates an overlap in categories, it should be submitted in a single communication. For example, a change in tablet potency would require other changes such as in components, composition, and labeling and should be submitted in a single communication.

(5) The following kinds of changes may be placed into effect without the approval of a supplemental application, if such change is fully described in the next periodic report required under § 514.80(b)(4) or, when such a report is